

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and
NOVO NORDISK A/S,

Plaintiffs,

v.

ORBICULAR PHARMACEUTICAL
TECHNOLOGIES PVT. LTD.,

Defendant.

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C.A. No. _____

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Novo Nordisk”), by their undersigned attorneys, for their Complaint against Defendant Orbicular Pharmaceutical Technologies Pvt. Ltd. (“Orbicular”), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Orbicular’s submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”), by which Orbicular seeks approval to market a generic version of Novo Nordisk’s pharmaceutical product Saxenda® prior to the expiration of United States Patent Nos. 7,762,994 (the “994 patent”), 8,114,833 (the “833 patent”), 8,579,869 (the “869 patent”), 8,684,969 (that “969 patent”), 8,920,383 (the “383 patent”), 9,108,002 (the “002 patent”), 9,132,239 (the “239 patent”), 9,457,154 (the “154 patent”), 9,616,180 (the “180 patent”), 9,687,611 (the “611 patent”), 9,775,953 (the “953 patent”), 9,861,757 (the “757 patent”), 10,220,155 (the “155 patent”), 10,357,616 (the “616 patent”), 10,376,652 (the “652 patent”), 11,097,063 (the “063

patent”), 11,311,679 (the “‘679 patent”), and RE46,363 (the “‘363 patent”) which cover *inter alia*, Saxenda® and/or its use.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. (“NNI”) is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

3. Plaintiff Novo Nordisk A/S (“NNAS”) is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

4. On information and belief, Defendant Orbicular Pharmaceutical Technologies Pvt. Ltd. is a company organized and existing under the laws of the Republic of India, having its principal place of business at P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar, Kukatpally, Hyderabad: 500 090, Telangana, India. On information and belief, Orbicular Pharmaceutical Technologies Pvt. Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendant Orbicular by virtue of, *inter alia*, having conducted business in Delaware; having derived revenue from conducting business in Delaware by marketing, selling, and/or distributing generic pharmaceutical drug products to

residents of Delaware; and having engaged in systematic and continuous contacts with the State of Delaware.

7. On information and belief, Orbicular develops, manufactures, imports, markets, offers to sell, sells, and/or distributes generic pharmaceutical products throughout the United States and in this District. On information and belief, Orbicular intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Orbicular's Product, directly or indirectly, throughout the United States and in this District. Orbicular's filing of Orbicular's ANDA confirms this intention and further subjects Orbicular to the specific personal jurisdiction of this Court.

8. If Defendant Orbicular's connections with Delaware are found to be insufficient to confer personal jurisdiction, then, on information and belief, Defendant Orbicular is not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over Defendant Orbicular in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

10. On July 27, 2010, the United States Patent and Trademark Office issued the '994 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '994 patent.

11. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and for Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '833 patent.

12. On November 12, 2013, the United States Patent and Trademark Office issued the '869 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '869 patent.

13. On April 1, 2014, the United States Patent and Trademark Office issued the '969 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '969 patent.

14. On December 30, 2014, the United States Patent and Trademark Office issued the '383 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '383 patent.

15. On August 18, 2015, the United States Patent and Trademark Office issued the '002 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '002 patent.

16. On September 15, 2015, the United States Patent and Trademark Office issued the '239 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the '239 patent.

17. On October 4, 2016, the United States Patent and Trademark Office issued the '154 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit H. NNAS is the owner of all right, title, and interest in the '154 patent.

18. On April 11, 2017, the United States Patent and Trademark Office issued the '180 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit I. NNAS is the owner of all right, title, and interest in the '180 patent.

19. On June 27, 2017, the United States Patent and Trademark Office issued the '611 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit J. NNAS is the owner of all right, title, and interest in the '611 patent.

20. On October 3, 2017, the United States Patent and Trademark Office issued the '953 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit K. NNAS is the owner of all right, title, and interest in the '953 patent.

21. On January 9, 2018, the United States Patent and Trademark Office issued the '757 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit L. NNAS is the owner of all right, title, and interest in the '757 patent.

22. On March 5, 2019, the United States Patent and Trademark Office issued the '155 patent, entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," a copy of which is attached to this Complaint as Exhibit M. NNAS is the owner of all right, title, and interest in the '155 patent.

23. On July 23, 2019, the United States Patent and Trademark Office issued the '616 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is

attached to this Complaint as Exhibit N. NNAS is the owner of all right, title, and interest in the '616 patent.

24. On August 13, 2019, the United States Patent and Trademark Office issued the '652 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit O. NNAS is the owner of all right, title, and interest in the '652 patent.

25. On August 24, 2021, the United States Patent and Trademark Office issued the '063 patent, entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," a copy of which is attached to this Complaint as Exhibit P. NNAS is the owner of all right, title, and interest in the '063 patent.

26. On April 26, 2022, the United States Patent and Trademark Office issued the '679 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit Q. NNAS is the owner of all right, title, and interest in the '679 patent.

27. On April 11, 2017, the United States Patent and Trademark Office issued the '363 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit R. NNAS is the owner of all right, title, and interest in the '363 patent.

SAXENDA®

28. NNI holds approved New Drug Application No. 206321 (the "Saxenda® NDA") for Saxenda® (liraglutide recombinant) Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Saxenda®.

29. The claims of the patents-in-suit cover, *inter alia*, Saxenda® and/or its use.

30. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '994, '833, '869, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, and '363 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Saxenda®.

ORBICULAR'S ANDA

31. On information and belief, Orbicular submitted ANDA No. 217234 ("Orbicular's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of liraglutide solution, for subcutaneous use, 18 mg/3 ml (6 mg/ml) ("Orbicular's Product").

32. On information and belief, Orbicular's ANDA refers to and relies upon the Saxenda® NDA and contains data that, according to Orbicular, demonstrate the bioequivalence of Orbicular's Product and Saxenda®.

33. By letter to NNI and NNAS, dated May 13, 2022 (the "First Notice Letter"), Orbicular stated that Orbicular's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '994, '833, '869, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, and '363 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Orbicular's Product (the "First Paragraph IV Certification"). Orbicular attached a memorandum to the First Notice Letter in which it purported to allege factual and legal bases for its First Paragraph IV Certification.

34. By letter to NNI and NNAS, dated June 9, 2022 (the "Second Notice Letter"), Orbicular stated that Orbicular's ANDA had been amended to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '679 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Orbicular's Product (the "Second Paragraph IV Certification"). Orbicular attached a memorandum to the Second Notice Letter in

which it purported to allege factual and legal bases for its Second Paragraph IV Certification. NNI and NNAS file this suit within 45 days of receipt of the First Notice Letter and within 45 days of receipt of the Second Notice Letter.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,762,994

35. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-34 of this Complaint.

36. Orbicular has infringed the '994 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '994 patent.

37. Claims 1-8 of the '994 patent are directed to a mounting system for mounting two different needle arrangements. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '994 patent would infringe claims 1-8 of the '994 patent.

38. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '994 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '994 patent expires.

39. Novo Nordisk has no adequate remedy at law.

40. Orbicular was aware of the '994 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,114,833

41. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-40 of this Complaint.

42. Orbicular has infringed the '833 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '833 patent.

43. Claims 1-15 of the '833 patent are directed to GLP-1 formulations. Claims 16-31 are directed to methods for preparing such formulations or methods of reducing deposits or reducing clogging by replacing the isotonicity agent in a formulation with propylene glycol. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent. Orbicular did not contest its infringement of any claims of the '833 patent, except to the extent that it contends that those claims are invalid.

44. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '833 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '833 patent expires.

45. Novo Nordisk has no adequate remedy at law.

46. Orbicular was aware of the '833 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,579,869

47. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-46 of this Complaint.

48. Orbicular has infringed the '869 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '869 patent.

49. Claims 1-6 of the '869 patent are directed to a needle mount for an injection device. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '869 patent would infringe claims 1-6 of the '869 patent.

50. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '869 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '869 patent expires.

51. Novo Nordisk has no adequate remedy at law.

52. Orbicular was aware of the '869 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,684,969

53. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-52 of this Complaint.

54. Orbicular has infringed the '969 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '969 patent.

55. Claims 1-26 of the '969 patent are directed to an injection device comprising a torsion spring operatively connected to a dose setting member and a rotatably mounted display member. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '969 patent would infringe claims 1-26 of the '969 patent.

56. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '969 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '969 patent expires.

57. Novo Nordisk has no adequate remedy at law.

58. Orbicular was aware of the '969 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,920,383

59. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-58 of this Complaint.

60. Orbicular has infringed the '383 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '383 patent.

61. Claims 1-12 of the '383 patent are directed to a mechanism for preventing setting of a dose which exceeds the amount of a medicament left in a reservoir in an injection device. Claim 13 of the '383 patent is directed to a syringe device employing such a mechanism. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '383 patent would infringe claims 1-13 of the '383 patent.

62. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '383 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '383 patent expires.

63. Novo Nordisk has no adequate remedy at law.

64. Orbicular was aware of the '383 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,108,002

65. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-64 of this Complaint.

66. Orbicular has infringed the '002 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '002 patent.

67. Claims 1-2 of the '002 patent are directed to an injection device with a release member opposite the end of the device where a needle may be mounted. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '002 patent would infringe claims 1-2 of the '002 patent.

68. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '002 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '002 patent expires.

69. Novo Nordisk has no adequate remedy at law.

70. Orbicular was aware of the '002 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,132,239

71. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-70 of this Complaint.

72. Orbicular has infringed the '239 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '239 patent.

73. Claims 1-3 of the '239 patent are directed to a dial-down mechanism for an injection device. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '239 patent would infringe claims 1-3 of the '239 patent.

74. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '239 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '239 patent expires.

75. Novo Nordisk has no adequate remedy at law.

76. Orbicular was aware of the '239 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,457,154

77. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-76 of this Complaint.

78. Orbicular has infringed the '154 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '154 patent.

79. Claims 1-17 of the '154 patent are directed to an injection device comprising a dose delivering mechanism which provides an audible feedback signal to a user at the end of injection of a set dose. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '154 patent would infringe claims 1-17 of the '154 patent.

80. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '154 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '154 patent expires.

81. Novo Nordisk has no adequate remedy at law.

82. Orbicular was aware of the '154 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,616,180

83. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-82 of this Complaint.

84. Orbicular has infringed the '180 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '180 patent.

85. Claims 1-14 of the '180 patent are directed to an injection device with a push button like release member opposite the end of the device where a needle may be mounted. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '180 patent would infringe claims 1-14 of the '180 patent.

86. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '180 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '180 patent expires.

87. Novo Nordisk has no adequate remedy at law.

88. Orbicular was aware of the '180 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,687,611

89. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-88 of this Complaint.

90. Orbicular has infringed the '611 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '611 patent.

91. Claims 1-13 and 15 of the '611 patent are directed to an injection device with a torsion spring operatively connected to a dose setting member and a rotatably mounted display member. Claim 14 of the '611 patent is directed to an injection pen comprising a torsion spring and a dose indicator barrel having a helical scale. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '611 patent would infringe claims 1-15 of the '611 patent.

92. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '611 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '611 patent expires.

93. Novo Nordisk has no adequate remedy at law.

94. Orbicular was aware of the '611 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,775,953

95. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-94 of this Complaint.

96. Orbicular has infringed the '953 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '953 patent.

97. Claims 1-10 and 12-25 of the '953 patent are directed to a mechanism for preventing setting of a dose which exceeds the amount of medicament left in a reservoir in an injection device. Claim 11 of the '953 patent is directed to a syringe device employing such a mechanism. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '953 patent would infringe claims 1-25 of the '953 patent.

98. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '953 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '953 patent expires.

99. Novo Nordisk has no adequate remedy at law.

100. Orbicular was aware of the '953 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,861,757

101. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-100 of this Complaint.

102. Orbicular has infringed the '757 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '757 patent.

103. Claims 1-12 of the '757 patent are directed to an injection device comprising a mechanism which provides a tactile feedback signal to a user at the end of injection of a set dose. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '757 patent would infringe claims 1-12 of the '757 patent.

104. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '757 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '757 patent expires.

105. Novo Nordisk has no adequate remedy at law.

106. Orbicular was aware of the '757 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,220,155

107. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-106 of this Complaint.

108. Orbicular has infringed the '155 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '155 patent.

109. Claims 1-8 of the '155 patent are directed to a syringe device with a dose limiting mechanism and a safety mechanism structure which prevent injection of a dose exceeding a set dose. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '155 patent would infringe claims 1-8 of the '155 patent.

110. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '155 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '155 patent expires.

111. Novo Nordisk has no adequate remedy at law.

112. Orbicular was aware of the '155 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,357,616

113. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-112 of this Complaint.

114. Orbicular has infringed the '616 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '616 patent.

115. Claims 1-9 of the '616 patent are directed to an injection device comprising a mechanism which provides an audible feedback signal to a user at the end of injection of a set

dose. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '616 patent would infringe claims 1-9 of the '616 patent.

116. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '616 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '616 patent expires.

117. Novo Nordisk has no adequate remedy at law.

118. Orbicular was aware of the '616 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,376,652

119. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-118 of this Complaint.

120. Orbicular has infringed the '652 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '652 patent.

121. Claims 1-15 of the '652 patent are directed to an injection device with a release member opposite the end of the device where a needle may be mounted, and a display member. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '652 patent would infringe claims 1-15 of the '652 patent.

122. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '652 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '652 patent expires.

123. Novo Nordisk has no adequate remedy at law.

124. Orbicular was aware of the '652 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 11,097,063

125. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-124 of this Complaint.

126. Orbicular has infringed the '063 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '063 patent.

127. Claims 1-7 of the '063 patent are directed to a syringe device with a dose limiting mechanism and a safety mechanism structure which prevent ejection of a dose exceeding a set dose. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '063 patent would infringe claims 1-7 of the '063 patent.

128. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '063 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '063 patent expires.

129. Novo Nordisk has no adequate remedy at law.

130. Orbicular was aware of the '063 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 11,311,679

131. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-130 of this Complaint.

132. Orbicular has infringed the '679 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '679 patent.

133. Claims 1-6 of the '679 patent are directed to an injection device with a release member on the end of the device opposite the end of the device where a needle may be mounted, and a display member. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '679 patent would infringe claims 1-6 of the '679 patent.

134. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '679 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '679 patent expires.

135. Novo Nordisk has no adequate remedy at law.

136. Orbicular was aware of the '679 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. RE46,363

137. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-136 of this Complaint.

138. Orbicular has infringed the '363 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Orbicular's ANDA, by which Orbicular seeks approval from the FDA to manufacture, use, offer to sell, and sell Orbicular's Product prior to the expiration of the '363 patent.

139. Claims 1-8 of the '363 patent are directed to dial-down mechanism for an injection device. Claims 9 and 10 of the '363 patent are directed to a medication delivery device comprising such a dial-down mechanism. Claim 11 of the '363 patent is directed to a method for using a wind up injection pen. Orbicular's manufacture, use, offer for sale or sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, during the term of the '363 patent would infringe claims 1-11 of the '363 patent.

140. Upon information and belief, Orbicular's sale or offer for sale of Orbicular's Product within the United States, or importation of Orbicular's Product into the United States, or commercial marketing of Orbicular's Product in the United States, during the term of and with knowledge of the '363 patent, would intentionally induce others to use Orbicular's Product in the United States, thus inducing infringement of claim 11 of the '363 patent.

141. Novo Nordisk will be harmed substantially and irreparably if Orbicular is not enjoined from infringing the '363 patent and/or if the FDA is not enjoined from approving Orbicular's ANDA before the '363 patent expires.

142. Novo Nordisk has no adequate remedy at law.

143. Orbicular was aware of the '363 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Orbicular and respectfully requests the following relief:

- A. A judgment that Orbicular has infringed the '994 patent;
- B. A judgment that Orbicular has infringed the '833 patent;
- C. A judgment that Orbicular has infringed the '869 patent;
- D. A judgment that Orbicular has infringed the '969 patent;
- E. A judgment that Orbicular has infringed the '383 patent;
- F. A judgment that Orbicular has infringed the '002 patent;
- G. A judgment that Orbicular has infringed the '239 patent;
- H. A judgment that Orbicular has infringed the '154 patent;
- I. A judgment that Orbicular has infringed the '180 patent;
- J. A judgment that Orbicular has infringed the '611 patent;
- K. A judgment that Orbicular has infringed the '953 patent;
- L. A judgment that Orbicular has infringed the '757 patent;
- M. A judgment that Orbicular has infringed the '155 patent;
- N. A judgment that Orbicular has infringed the '616 patent;
- O. A judgment that Orbicular has infringed the '652 patent;
- P. A judgment that Orbicular has infringed the '063 patent;
- Q. A judgment that Orbicular has infringed the '679 patent;

R. A judgment that Orbicular has infringed the '363 patent;

S. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Orbicular's ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '994, '833, '869, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, and '363 patents, including any extensions, adjustments, and exclusivities;

T. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Orbicular, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Orbicular's Product within the United States, or importing Orbicular's Product into the United States, prior to the expiration of the '994, '833, '869, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, and '363 patents, including any extensions, adjustments, and exclusivities;

U. If Orbicular commercially manufactures, uses, offers to sell, or sells Orbicular's Product within the United States, or imports Orbicular's Product into the United States, prior to the expiration of the '994, '833, '869, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, and '363 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

V. An award of attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

W. An award of costs and expenses in this action; and

X. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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June 24, 2022